

**REMARKS**

**Office Action Summary**

Claims 1-5 and 8-18 are pending; each of the pending claims has been rejected.

On the Office Action Summary sheet the Examiner lists claims 1-5 and 8-15 as pending in the application. Applicants respectfully note, however, that claims 1-5 and 8-18 are pending in the application. While a PCT Article 34 amendment was filed in this application, it only cancelled claims 6-7. Thus, claims 1-5 and 8-18 are each still pending in the application.

**The Invention**

The adhesive agent composition of the present invention comprises:

- (A) 50 to 90% by weight of an acrylic adhesive agent;
- (B) 2.5 to 50% by weight of a polyhydric alcohol-containing liquid component, and
- (C) 0.01 to 10% by weight of an aliphatic acid metal salt formed from an aliphatic acid that has a hydrocarbon group containing from 8 to 18 carbon atoms and a mono- to tri-valence metal.

The polyhydric alcohol-containing liquid component (B) contains, in addition to the polyhydric alcohol (B-a), at least one sorbitan ester compound (B-b) selected from sorbitan esters and poly(oxyalkylene) sorbitan esters of aliphatic acids having a hydrocarbon group having 12 to 18 carbon atoms, in an amount of 0.5 to 20% by weight based on the total weight of the composition.

Thus, it is essential that, in the adhesive agent composition of the present invention, the at least one sorbitan ester compound (B-b) as defined in claim 1 is present as an additional moiety to the polyhydric alcohol moiety (B-a), in the polyhydric alcohol-containing liquid moiety (B).

Also, it is essential that the liquid component (B) containing the polyhydric alcohol (B-a) and the sorbitan ester compound (B-b) be present in combination with the aliphatic acid metal salt (C) as defined in claim 1, in the adhesive agent composition of the present invention containing, as a principal adhesive component, an acrylic adhesive agent (A).

Importantly before the present invention was completed, it was known that polyhydric alcohols and sorbitol ester compounds present in adhesive agent compositions cause a reduction in the cohesive force of the resultant adhesive agent composition. See the passage on page 2, lines 16 to 35, of the specification. Also, it was known that metal salts may cause a reduction in cutaneous absorption of the drug contained in the adhesive agent composition due to interaction between the drug and the metal salts. See the passage on page 3, lines 15-27, of the specification.

With the present invention, however, it was found, for the first time, that the combination of the polyhydric alcohol (B-a) with the specific sorbitan ester compound (B-b) and the specific aliphatic acid metal salt (C), as defined in claim 1, enables the resultant acrylic adhesive resin (A)-containing adhesive agent composition to exhibit all of: enhanced cohesive force, moisture-permeability, and a high cutaneous absorption of drugs.

#### **Detailed Action**

Claims 1-5 and 8-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of JP Publication No. 09-143062 (hereinafter "'062"), JP Publication No. 04-

266742 (hereinafter “‘742”), International Publication No. WO 92/10154 (hereinafter “‘154”), and JP Publication No. 01-233212 (hereinafter “‘212”).

In the Office Action, the Examiner asserted that each of ‘062 and ‘742 discloses a pressure sensitive adhesive composition that contains the claimed amounts of each component of the claimed adhesive agent composition, other than the sorbitan ester compound. However, the Examiner asserted that the ‘154 and ‘212 disclose the “idea” of adding a sorbitan ester compound as a skin drug absorption promoter in about the amount claimed. Accordingly, the Examiner concluded that by combining both references, the claimed adhesive composition is taught.

For the following reasons, the rejection is traversed, respectfully.

1. JP-A-09-143062 (Reference ‘062)

Reference ‘062 discloses a tacky agent composition for percutaneous application and its production comprising (a) an acrylic adhesive polymeric agent soluble in a lower alcohol, (b) a mixture of a lower alcohol with a polyhydric alcohol, and (c) a metal soap. Reference ‘062 is devoid of any teachings about including a sorbitan ester compound as a component of the tacky agent composition.

Also, Reference ‘062 does not teach or suggest the combination of the polyhydric alcohol (B-a) with the sorbitan ester compound (B-b) and the aliphatic acid metal salt (C) and the specific effect of the combination.

2. JP-A-4-266,742 (Reference ‘742)

Reference ‘742 discloses a medical conductive adhesive agent comprising a blend polymer of a vinyl pyrrolidone (co)polymer with a (meth)acrylic acid copolymer except for

(meth)acrylic acid (salt)alkyl (meth)acrylate ester copolymers, an electrolyte (for example, NaCl, KCl, CaCl<sub>2</sub>) and a softening agent (for example, a polyhydric alcohol and derivatives thereof.

Reference '742 is devoid of any teachings as to use of a sorbitan ester compound as a component of the adhesive agent. Also, Reference '742 does not teach or suggest the combination of the polyhydric alcohol (B-a) with the sorbitan ester compound (B-b) and the aliphatic acid metal salt (C) and the specific effect of the combination.

3. WO 92/10154 (Reference '154)

Reference '154 discloses a system for administering a drug transdermally using sorbitan esters as a skin permeation enhancer.

Reference '154 discloses a drug administering system containing an adhesive composition comprising an acrylic polymer adhesive, an aliphatic monohydric alcohol (for example, ethyl alcohol) and a sorbitan ester.

The adhesive composition contains no polyhydric alcohol. Also, Reference '154 does not teach or suggest the combination of the polyhydric alcohol (B-a) with the sorbitan ester compound (B-b) and the aliphatic acid metal salt (C) and the specific effect of the combination.

4. JP-A-233,212 (Reference '212)

Reference '212 discloses a plaster for application to skin and having a tacky adhesive layer containing a drug, an adhesive agent, lecithin and/or a sorbitan fatty acid salt and a specific absorbent. The adhesive agent comprises, as a principal component, an alkyl(meth)acrylate ester or copolymer thereof with a polar monomer.

Reference '212 is devoid of any teachings as to use of a polyhydric alcohol as a component in the tacky adhesive layer. Also, Reference '212 contains no metal soap. Further, Reference '212 does not teach or suggest the combination of the polyhydric alcohol (B-a) with the sorbitan ester compound (B-b) and the aliphatic acid metal salt (C) and the specific effect of the combination.

5. Reference '062 and '742 are devoid of any teachings as to use of a sorbitan ester compound (B-b) in an adhesive agent composition and therefore as to use of a combination of the sorbitan ester component (B-b) with the polyhydric alcohol (B-a) and the aliphatic carboxyl acid metal salt (C) and the specific effect of the combination.

Reference '212 and '154 are devoid of any teachings as to use of the polyhydric alcohol (B-a) and the aliphatic carboxyl acid metal salt (C) in an adhesive agent composition, and thus as to use of a combination of the sorbitan ester compound (B-b) with the polyhydric alcohol (B-a) and the aliphatic carboxyl acid metal salt (C), and the specific effect of the combination.

Accordingly, the cited references provide no motivation to combine the sorbitan ester compound (B-b) with the polyhydric alcohol (B-a) and the aliphatic carboxyl acid metal salt (C), as required by the present claims.

Therefore, Applicants assert that none of the cited references, alone or in combination, make obvious the claimed invention and Applicants respectfully request reconsideration and withdrawal of this rejection

### **Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

RESPONSE UNDER 37 C.F.R. § 1.111  
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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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